

Notice of Allowability

Application No.

10/070,365

Examiner

Hector M Reyes

Applicant(s)

OZAKI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11-26-2003.
2. ☒ The allowed claim(s) is/are 1, 52, 53, 63 and 72, renumbered as 1-5.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other _____ |

DETAILED ACTION

Status of the Claims

Claims 2-51, 54-62, 64-71 and 73-82 have been canceled. Claims 1, 52-53, 63 and 72 have been amended. Currently claims 1, 52-53, 63 and 72 are under examination. The said active claims have been renumbered as claims 1 to 5.

Allowance

The following is an examiner's statement of reasons for allowance: Applicants claim:

- In renumbered claims 1 and 4 a process for the producing optically active 4-amino-2-methylbutane -1-ol, as described in the said claims.
- In renumbered claim 2 and 3 a salt of optically active 4-amino-2-methylbutane -1-ol with an optically active organic acid and a process for producing a salt of optically active 4-amino-2-methylbutane -1-ol with an optically active organic acid as described in the said claims.
- In renumbered claim 5, a process for recovering an optically active reagent used in producing optically active 4-amino-2-methylbutane-1-ol as described in the said claim.

No prior art disclosing or suggesting the claimed instant process was found in the prior art. The closest art relevant to the instant invention was found in Kazan et al, US patent 4259521.

Kazan discloses a process for the resolution of (d, l) mandelic acid using optically active 2-amino-1- butanol using water or a lower aliphatic alcohol or mixtures thereof, such method comprising (see col. 1 and 2):

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- Reacting (d, l) mandelic acid with optically active 2-amino-1-butanol in the said solvents or mixtures thereof, in order to form the corresponding diastereoisomeric salts
- Separation of the said salts
- Liberation of the optically active substance by conventional acid-base reactions
- Variations to the said process in directed to improve the resolution.

Kazan however, does not disclose the use of (R) or (S)-4-amino-2-methylbutane-1-ol as the resolving agent in the said resolution, nor the resolution of 4-amino-2-methylbutane-1-ol using (R) or (S) mandelic acid enantiomers as resolving agents.

CONCLUSION

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee.

Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

All post-Allowance Correspondence concerning this Application must be mailed to:

**BOX ISSUE FEE
COMMISSIONER FOR PATENTS
WASHINGTON, DC 20231**

Or you can fax them to the Office of Patent Publications at 703-308-5083, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312; information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

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For information concerning status of correspondence sent after receipt of the Notice of


Allowance, please contact the Correspondence Branch at (703) 305-8027.

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Reg. # 54,846

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January 19, 2004



PAUL J. KILLOS
PRIMARY EXAMINER